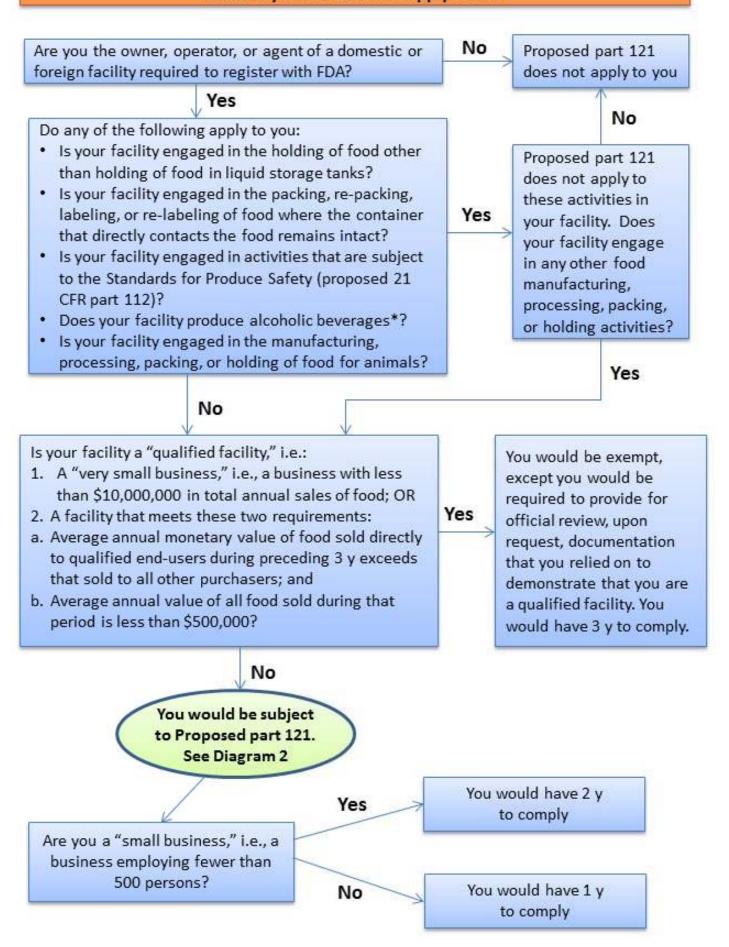
Diagram 1. Would proposed 21 CFR part 121 to protect against intentional adulteration caused by acts of terrorism apply to me?



^{*}See proposed 121.5(e) for specific conditions

Diagram 2. Proposed Requirements

Proposed 21 CFR part 121

A. Written Food Defense

Plan that includes:

- 1. Actionable Process Steps
- Focused Mitigation Strategies
- 3. Monitoring
- 4. Corrective Actions
- 5. Verification
- B. Training of supervisors and personnel working at actionable process steps
- C. Records to be prepared and kept

1. Actionable Process Steps

Assess whether your facility has one or more of these FDA-identified key activity types*:

Option 1

- 1.Bulk liquid receiving and loading
- 2.Liquid storage and handling
- 3.Secondary ingredient handling
- 4.Mixing and similar activities

Identify actionable process steps for each applicable key activity Perform a vulnerability assessment using appropriate methods and qualified individual(s)

Option 2

Identify and prioritize points in food operation that are vulnerable to intentional adulteration

Identify actionable process steps for significant vulnerabilities

5. Verification

Verify that monitoring is conducted

Verify that appropriate decisions about corrective actions are made

Verify that focused mitigation strategies are consistently implemented and are effective

Conduct reanalysis of the food defense plan, as appropriate

2. Focused Mitigation Strategies

Identify and implement focused mitigation strategies at actionable process steps

3. Monitoring

Establish and implement procedures for monitoring focused mitigation strategies

4. Corrective Actions

Establish and implement procedures for corrective actions if focused mitigation strategies are not properly implemented

^{*}FDA identified these key activity types using findings of vulnerability assessments of over 50 food products and processes. These activity types commonly rank high in vulnerability based on various factors, including the ability to physically access the food or process and the potential to adulterate a sufficient quantity of product in order to cause massive public health harm.